

Message

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Sent: 7/2/2019 12:23:31 PM
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Subject: RE: ReCAAP - telecon to review waivers and reporting template
Attachments: Comments on the DRAFT SYN1 Waiver_.docx

Dear Cancer Waiver Team,

I have a proposal for discussion at our next meeting.

I have received approval from our senior leadership to provide prospective cancer waivers for upcoming Als that have not yet been registered but that we already have the bioassay results or will shortly. Our thought at Syngenta is that if we truly wish to move this forward more rapidly doing retrospective reviews, while important for acceptance, don't provide the necessary uncertainty in analysis that a review of a true unknown would.

Our senior leadership are supportive with the following stipulation which we suggest is applicable for any registrant who supplies a draft prospective waiver.

Draft waivers on a non-registered chemical will be considered CBI.
The initial report from EPA specific to the waiver will also be considered CBI.

In order to progress the project the registrant who provides a prospective waiver will work with EPA to provide a summary document of the EPA review of the waiver which points out data sufficiency and data deficiency within the waiver.

This should still aid in achieving our overarching goal to develop waiver guidance which includes the kind of data that needs to be collected and presented in order to achieve confidence in health protection without the bioassay.

For example. We may present a mode of action but the EPA feels we are missing cell proliferation data in the liver at earlier time points. Such information is critical to all participants and gives no usable information to the other registrants specific to a chemical.

In evaluating the review document that EPA provided on our initial example, which was the AI Adepidyn, there is actually very little information in EPA's review document that is chemical specific and would be considered actual CBI, thus the above proposal should have little impact on achieving the goals of this project.

I will be interested in hearing your thoughts at the upcoming discussion on July 12th.

doug

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